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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,595	05/08/2001	Wei Gu	MNI-080CP	2613

7590 09/30/2002
INTELLECTUAL PROPERTY GROUP
MILLENNIUM PHARMACEUTICALS, INC.
75 SIDNEY STREET
CAMBRIDGE, MA 02139

EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/851,595

Applicant(s)
Wei Gu

Examiner
Prema Mertz

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1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 26, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-IV. Claims 1-7, 12, drawn to a nucleic acid encoding a polypeptide of SEQ ID NO:2, 5, 8 or 11, a vector, a host cell and a method for producing the polypeptide, classified in class 435, subclass 69.1.

V-VIII. Claims 8-10, drawn to a polypeptide of SEQ ID NO:2, 5, 8 or 11, classified in class 530, subclass 350.

IX-XII. Claim 11, drawn to antibody to a polypeptide of SEQ ID NO:2, 5, 8 or 11, classified in Class 530, subclass 387.1.

XIII-XVI. Claims 13-15, drawn to a method of detecting the presence of a polypeptide of SEQ ID NO:2, 5, 8 or 11, using an antibody to the polypeptide, classified in Class 435, subclass 7.2.

XVII-XX. Claims 16-18, drawn to a method of detecting the presence of a nucleic acid encoding a polypeptide of SEQ ID NO:2, 5, or 8, using a nucleic acid probe or primer, classified in Class 435, subclass 6.

XXI-XXIV. Claims 19-22, drawn to a method of identifying a compound which binds to a polypeptide of SEQ ID NO:2, 5, 8 or 11, classified in Class 435, subclass 7.1.

Should any one of the Groups from I-XXIV be elected, Applicant is required to select one amino acid sequence from SEQ ID NO:2, 5, 8 or 11.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I-XII, are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. Each of the polynucleotides of Groups I-IV can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the specific protein of interest. Each of the proteins of inventions V-VIII can be used as a probe, or used therapeutically or diagnostically, e.g. in screening. Each of the antibodies of inventions IX-XII can be used to obtain the polynucleotides of Groups I-IV, and can also be used in diagnostics, e.g. as a probe in immunoassays. The antibody of invention IX can only be used to bind the protein of invention V, not the protein of invention VI, VII or VIII. Similarly, the nucleic acid of invention I, can only be used to produce the protein of invention V, not the protein of invention VI, VII or VIII.

Inventions I-IV and V-VIII are related as processes of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP. § 806.05(f)). In the instant case the proteins can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions IX-XII and XIII-XVI are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using

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the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product of inventions IX-XII can also be used in immunochromatography.

Inventions V-VIII and XXI-XXIV are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions V-VIII can also be used as antigens in the production of antibodies.

Inventions I-IV and XVII-XX are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products of inventions I-IV can also be used in gene therapy.

Inventions I-IV and XIII-XVI, XXI-XIV, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions V-VIII and XIII-XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they

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have different functions, or they have different effects. (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions IX-XII and XVII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP. § 806.04, MPEP. § 808.01). In the instant case the different inventions are not disclosed as capable of use together.

Inventions XIII-XIV are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP. § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP. § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
August 6, 2002